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NOT TO BE PUBLISHED IN OFFICIAL REPORTS

IN THE COURT OF APPEAL OF THE STATE OF CALIFORNIA

FIRST APPELLATE DISTRICT

DIVISION FIVE

FLORENCE KUHLMANN, et al., Plaintiffs and Respondents, v. ETHICON ENDO-SURGERY LLC, et al., Defendants and Appellants, RAKHEE N. SHAH, Defendant and Respondent.	A147945 (Alameda County Super. Ct. No. RG13675753)

Plaintiffs Florence Kuhlmann and her husband John Perkins (Plaintiffs) sued Ethicon Endo-Surgery LLP; Johnson & Johnson Health Care Systems, Inc. (collectively, Ethicon); and Dr. Rakhee N. Shah after Kuhlmann suffered severe complications from a surgery performed by Dr. Shah using a medical device manufactured and distributed by Ethicon. Ethicon appeals from jury verdicts finding Ethicon liable for compensatory and punitive damages, arguing certain evidence was erroneously admitted, there was juror misconduct, and the punitive damages award lacks substantial evidence and is excessive. We reduce the punitive damages award and otherwise affirm.

BACKGROUND

The Stapler

Ethicon manufactures the PPH03 Hemorrhoidal Circular Stapler (the Stapler) for use in a hemorrhoidopexy, a certain type of hemorrhoid surgery. The Stapler is inserted

into the patient's rectum and when the surgeon squeezes the firing lever, a blade cuts out a ring-shaped portion of tissue and a circular line of staples fix the remaining tissue within the anal canal. A cracking noise from the breaking of a washer alerts the surgeon that the Stapler has fired. The Stapler's instructions direct surgeons not to fire the device more than once and warn that additional firings could result in tissue damage.

The Stapler was designed in 2003 as a modification of another stapler manufactured by Ethicon, the PPH01 Hemorrhoidal Circular Stapler. The Stapler's final design included specifications about "force to fire"—the force required by a surgeon to squeeze the firing lever and fully deploy the staples and knife. These specifications established upper and lower limits on the force to fire. The Stapler's lead design engineer testified that excessive force to fire becomes an issue when the surgeon cannot complete the firing stroke, resulting in staples that are not fully formed.[1] In a 2003 design review document, the lead design engineer recommended that a "control plan" be put in place to measure the Stapler's force to fire over time and ensure that it remained within the specifications. A "force to fire station," established at the Stapler manufacturing plant, measured and recorded the force to fire of each Stapler coming off the assembly line. However, prior to 2012, Ethicon did not look at the measurements or discard Staplers that did not meet the force to fire specifications. No other steps were taken during this time to ensure the force to fire of manufactured Staplers met the design specifications. Plaintiffs' expert in biomedical engineering testified the force to fire requirements were a critical specification of the Stapler's design, and Ethicon's failure to enforce its own force to fire specifications was "outrageous" and "[w]ay below" industry standards.

Between 2004 and 2012, Ethicon received reports from physicians about difficulty firing Staplers, difficulty removing Staplers after firing, incomplete stapling or cutting, malformed staples, and having to fire more than once. Plaintiffs presented evidence of hundreds of such reports; Ethicon sold approximately 1.2 million Staplers during this

[1] The testimony of this witness and several others was presented by showing the jury a videotape of the witnesses' deposition testimony. Some deposition testimony was also read to the jury.

period. Ethicon reviewed and investigated these reports, soliciting more information from the reporting physicians when it deemed necessary, and attempting to retrieve and inspect the Staplers involved. In monthly meetings, Ethicon employees reviewed reports from the previous one or two years to look for trends in the device's performance.

In 2007, Ethicon received reports of Staplers being too hard to fire and incompletely firing. After examining returned Staplers, Ethicon determined that glue had migrated into the casing and hardened, making the Stapler harder to fire and giving surgeons tactile and audible feedback from the cracking glue that led them to think they had completed the firing stroke when in fact they had not. The glue hardening did not occur at Ethicon's manufacturing facility, but only during a later sterilization process at a facility located elsewhere. Ethicon voluntarily recalled all lots with affected Staplers and revised its inspection process to check for migrated glue that could later harden and cause the problem, but did not implement a system for checking the devices' force to fire.

In April 2011, Ethicon changed the lubrication process from submerging the Staplers in lubricant to brushing the lubricant on by hand.[2] Despite knowing that inadequate lubrication could increase the force to fire, Ethicon conducted no testing to determine how the 2011 lubrication change would affect force to fire. Plaintiffs' expert testified Ethicon's failure to conduct such testing was below industry standards. In September or October 2011, Ethicon noted an increase in complaints about Staplers. Many of the complaints indicated excessive force to fire, and upon analyzing the returned devices, Ethicon determined the firing stroke had not been completed. In May 2012, Ethicon initiated a process to determine whether corrective action was needed to address the problem. In July or August 2012, Ethicon determined the problem was caused by the change in its lubrication process, which resulted in some Staplers receiving less lubrication and therefore requiring greater force to fire. Ethicon reached this conclusion after analyzing the force to fire data that had previously been collected, but not

[2] The change was initiated in response to physician complaints about rust on Staplers, which Ethicon attributed to the submersion method of applying lubrication.

monitored, at the manufacturing plant. If Ethicon had previously been monitoring these force to fire measurements, it would have discovered the increased force to fire earlier.

In August 2012, Ethicon voluntarily recalled all lots affected by the changed lubrication method. The FDA's recall notice identified the reasons for the recall as follows: "Users have difficulty firing the stapler devices, resulting in incomplete firing stroke and incomplete staple formation. [¶] Failure to complete the firing stroke of the stapler can result in severe pain, sphincter dysfunction, rectal wall damage, sepsis, bleeding, and occlusion of the rectal canal. Failure to complete the firing stroke can also result in poor staple formation, dehiscence of the rectal wall staple line and bleeding. [¶] This product may cause serious adverse health consequences, including death." After the 2012 recall, Ethicon adopted a pass/fail force to fire requirement for all Staplers coming off its assembly line. Any Stapler with a force to fire measurement greater than the maximum specification is rejected and not released for sale.

Kuhlmann's Surgery and Complications

In January 2012, Dr. Shah performed a hemorrhoidopexy on Kuhlmann using a Stapler. Dr. Shah had previously performed about 35 hemorrhoidopexies using Staplers without any problems. After Dr. Shah fired the Stapler during Kuhlmann's surgery, she could not remove the device. Dr. Shah believed the Stapler had not fired the first time. Dr. Shah decided to fire the Stapler again to free the device; the only other option would have been to cut it out. Using all of her strength, she fired the device a second time and was then able to remove it. Dr. Shah examined Kuhlmann and saw some loose staples, but believed the surgery was successful. However, it was subsequently discovered that Kuhlmann's rectum had been stapled closed during the surgery. As a result, Kuhlmann had a colostomy, followed by multiple surgeries unsuccessfully attempting to repair her rectum and reverse the colostomy. She has a permanent colostomy bag which has severely impaired her quality of life.

Dr. Shah did not retain the Stapler used in Kuhlmann's surgery. The facility where Kuhlmann's surgery was performed ordered Staplers when there were none left from the previous order. Between November 2010 and January 2012, the facility

received only two orders of Staplers, each with a single box of three Staplers. Both orders came from lots that were subsequently part of the 2012 recall. One of the boxes came from a recalled lot in which one-third of the Staplers did not meet the force to fire specifications. The other box came from a recalled lot in which 30 out of 217 Staplers exceeded the force to fire specifications. Plaintiffs' biomedical engineering expert testified Dr. Shah's experience with the Stapler used in Kuhlmann's surgery was consistent with the defective Staplers recalled in 2012.

Proceedings Below

Plaintiffs sued Dr. Shah and Ethicon. The jury found Ethicon was liable for manufacturing defects, failure to warn, and negligence; it found Ethicon not liable for design defects and found Dr. Shah was not negligent. The jury awarded Kuhlmann approximately $525,000 in economic damages and $8 million in past and future noneconomic damages. Perkins, Kuhlmann's husband, was awarded $1.3 million for past and future loss of consortium damages. The jury found Ethicon acted with malice and, following a bifurcated trial on the amount of punitive damages, awarded Plaintiffs $70 million in punitive damages. The trial court denied Ethicon's motions for a new trial and judgment notwithstanding the verdict.

DISCUSSION

I. *Evidentiary Challenges*

Ethicon argues the trial court erred in admitting two categories of evidence: evidence of other incidents reported to Ethicon about its circular staplers, and evidence of the 2007 recall. We reject both challenges.

"Evidentiary rulings, including those made in limine, are reviewed for abuse of discretion. [Citation.] . . . . [¶] However, even if evidence is improperly admitted, '[n]o judgment shall be set aside, or new trial granted . . . unless, after an examination of the entire cause . . . the court shall be of the opinion that the error complained of has resulted in a miscarriage of justice.' [Citations.] A 'miscarriage of justice' occurs when the party appealing shows that a 'different result would have been probable if the error had not

occurred.' " (*Colombo v. BRP US Inc.* (2014) 230 Cal.App.4th 1442, 1474–1475 (*Colombo*).)

A. *Other Incidents*

1. *Background*

Ethicon filed a motion in limine seeking to exclude evidence "concerning any injury, complaint, or adverse event relating to [the Stapler] or any other of [Ethicon's] staplers that involve persons other than plaintiff Florence Kuhlmann." The motion noted Plaintiffs had obtained in discovery Ethicon files regarding other incidents involving Ethicon staplers (including staplers other than the Stapler) that had been reported to Ethicon, and argued such evidence was hearsay, insufficiently similar and thus irrelevant, and unduly prejudicial. Plaintiffs identified 253 reports of incidents from 2003 to 2014 involving "[d]ifficulty firing the device, rectal occlusion, surgeons firing the device twice," and "being stuck in the patient," which they argued were sufficiently similar to Kuhlmann's surgery to constitute evidence of notice and defect. Plaintiffs also argued the Stapler was sufficiently similar to two other staplers—the PPH01 and STR10—to warrant admission of incidents about these staplers as evidence of notice. Plaintiffs contended incidents reported to Ethicon after Kuhlmann's 2012 surgery were relevant as evidence of defect and for punitive damages.

The trial court ruled as follows: "As to complaints having to do with the stapler (whether version used in the Kuhlmann surgery or other related staplers) the firing (misfiring), rectal occlusion, firing more than one time per stapler, and/or the stapler being lodged within the patient in regards to PPH03, PPH01, and STR10, the [motion in limine] is DENIED. As to any other complaints, it is GRANTED. Counsel are to promptly meet and confer regarding any limiting instructions, for example regarding complaints after the date of the subject incident." No such limiting instructions were requested or issued.

At trial, Plaintiffs introduced more than 200 Ethicon "complaint files" involving reports Ethicon received about incidents with the Stapler between 2004 and 2014. They also introduced more than 600 pages of Ethicon files about incidents primarily involving

the PPH01 and STR10 staplers, and an Ethicon-created spreadsheet compiling information from incident files. Plaintiffs questioned an Ethicon employee about many of the incident files in evidence. Plaintiffs' biomedical engineering expert testified there were "numerous complaints from surgeons that they found the force to fire excessive and/or couldn't complete the stroke and/or got stuck," and these were consistent with what happened in Kuhlmann's surgery.

2. *Forfeiture*

As an initial matter, Plaintiffs argue Ethicon forfeited its challenge to all but two of the Stapler incident files and to the Ethicon employee's testimony because it failed to identify any specific incidents it was objecting to in the in limine motion and failed to object to the admission of this evidence at trial.

"[A] motion *in limine* to exclude evidence is a sufficient manifestation of objection to protect the record on appeal when it satisfies the basic requirements of Evidence Code section 353, i.e.: (1) a specific legal ground for exclusion is advanced and subsequently raised on appeal; (2) the motion is directed to a particular, identifiable body of evidence; and (3) the motion is made at a time before or during trial when the trial judge can determine the evidentiary question in its appropriate context. When such a motion is made and denied, the issue is preserved for appeal." (*People v. Morris* (1991) 53 Cal.3d 152, 190 (*Morris*), disapproved of on another ground by *People v. Stansbury* (1995) 9 Cal.4th 824, 830, fn. 1.) Ethicon's motion in limine identified a specific body of evidence—Ethicon's files and other evidence produced in discovery about stapler incidents other than the one involving Kuhlmann—which the trial court was able to consider in its appropriate context. We therefore reject Plaintiffs' claim that the challenge in its entirety is forfeited.

3. *Hearsay*

Ethicon argues the records about other stapler incidents are hearsay. The records were prepared by Ethicon employees and document statements by third parties, usually physicians, reporting incidents involving staplers.

Dr. Shah argues the documents are admissible as business records. (See Evid. Code, § 1271.) However, the records involve multiple hearsay: the third party's statement about what happened with the stapler, and Ethicon's documentation of that statement. (See *People v. Ayers* (2005) 125 Cal.App.4th 988, 995 [domestic violence organization's records contained multiple hearsay: "[the victim's] statements to the [organization's] employee was the first hearsay layer and the employee's recordation of those statements was the second hearsay layer"].) " 'When multiple hearsay is offered, an exception for *each* level of hearsay must be found in order for the evidence to be admissible.' " (*Ibid*.) While the business record exception applies to Ethicon's documentation of the third parties' reports, it does not apply to the underlying statements made by the third parties. (See *People v. Hernandez* (1997) 55 Cal.App.4th 225, 240 ["the business records exception has been held inapplicable to admit police reports into evidence for the sheer reason such are or might be based upon the observations of victims and witnesses who have no official duty to observe and report the relevant facts"].) Thus, while the business records exception renders admissible the evidence that incidents were reported to Ethicon, it does not render admissible the evidence that the incidents in fact took place.

Dr. Shah argues that Ethicon "regularly verified the complaints" and therefore the underlying statements contained in the incident files constitute adoptive admissions by Ethicon. (See Evid. Code, § 1221 ["Evidence of a statement offered against a party is not made inadmissible by the hearsay rule if the statement is one of which the party, with knowledge of the content thereof, has by words or other conduct manifested his adoption or his belief in its truth."].) The evidence reflects Ethicon attempted to obtain additional information about the incidents, analyze returned devices, and identify the cause of problems. Such investigations do not constitute adoptive admissions, particularly where, as is the case in at least several of the incident files, Ethicon's investigation concluded that the incident "could not be confirmed."

Plaintiffs argue the incident files were not hearsay to prove Ethicon had notice of the Stapler defect and/or the inadequacy of its quality control process. Ethicon does not

dispute that when used for such purposes, the files are not hearsay. (See 1 Witkin, Cal. Evidence (5th ed. 2012) Hearsay, § 42 ["Statements of a third person concerning a dangerous condition are admissible for the limited purpose of showing knowledge on the part of the defendant who heard them, though they are inadmissible hearsay on the issue whether there was in fact a defect or dangerous condition."].) Plaintiffs further argue that, by failing to seek a limiting instruction limiting the evidence to such purposes, Ethicon forfeited any argument that the evidence was inadmissible for other purposes. We disagree. Ethicon's motion in limine argued the evidence was hearsay; at the hearing Plaintiffs clearly stated they intended to use the incident files as evidence of both notice and defect. The trial court denied Ethicon's motion outright as to the specified types of incidents. Ethicon's motion in limine thus preserved its argument that the records constituted inadmissible hearsay. (*Morris, supra,* 53 Cal.3d at p. 190.) Plaintiffs note that the trial court's order indicated its willingness to issue limiting instructions, but there was no discussion at the hearing about limiting the use of the evidence to notice and the order identified only "complaints after the date of the subject incident" as an example of evidence for which it would issue a limiting instruction.

We thus conclude the trial court erred in admitting Ethicon's files and records about other stapler incidents as evidence that the Stapler used in Kuhlmann's surgery was defective. However, the error was harmless in light of evidence of the 2012 recall, the admission of which Ethicon does not challenge on appeal. Plaintiffs' theory was that the Stapler used in Kuhlmann's surgery was one of the defective Staplers subject to the 2012 recall. The 2012 recall notice identified the problem as physicians having "difficulty firing the stapler devices, resulting in incomplete firing stroke and incomplete staple formation," which "can result in . . . occlusion of the rectal canal." Plaintiffs submitted evidence that the Stapler used in Kuhlmann's surgery came from a lot later subject to the 2012 recall, and Plaintiffs' expert opined that Dr. Shah's experience with the Stapler used in Kuhlmann's surgery was consistent with the defective Staplers recalled in 2012.

In closing arguments, Plaintiffs' counsel argued: "What do we know about the specific stapler that was used in Miss Kuhlmann's surgery? The evidence is that that

stapler was recalled." Plaintiffs proceeded to discuss in detail the evidence that the surgery center received Staplers from recalled lots in the several months prior to Kuhlmann's surgery and the percentage of defective Staplers in those recalled lots. Plaintiffs recounted Dr. Shah's problem with the Stapler during Kuhlmann's surgery and argued it was "the same problem for which Ethicon ultimately recalled the stapler. [¶] You remember this is the notice to the FDA. Ethicon told the FDA that users have difficulty firing the stapler resulting in incomplete firing stroke and incomplete staple formation," and "Dr. Shah had difficulty firing the stapler" in Kuhlmann's surgery. Although Plaintiffs' closing argument also discussed "all the complaints" and argued "the force to fire problem always existed. It just got much, much worse with the lubrication change [resulting in the 2012 recall]," their primary theory on defect was that the Stapler used in Kuhlmann's surgery was one of the Staplers recalled in the 2012 recall and there was ample evidence supporting this theory. We conclude it is not reasonably probable the verdicts would have been different had the trial court not erred in admitting hearsay records about other incidents as evidence of defect.

4. *Relevance*

Ethicon argues the other incidents reported to Ethicon are not sufficiently similar to Kuhlmann's surgery to be relevant to the issue of notice.

"Evidence of prior accidents is admissible to prove a defective condition, knowledge, or the cause of an accident, provided that the circumstances of the other accidents are similar and not too remote." (*Elsworth v. Beech Aircraft Corp.* (1984) 37 Cal.3d 540, 555 (*Elsworth*).) "When evidence is offered to show only that defendant had notice of a dangerous condition, the requirement of similarity of circumstances is relaxed: ' "all that is required . . . is that the previous injury should be such as to attract the defendant's attention to the dangerous situation . . . ." ' " (*Hasson v. Ford Motor Co.* (1982) 32 Cal.3d 388, 404 (*Hasson*).) To admit evidence that the defendant "had received other claims of . . . injuries" to show "[the defendant], before the injury to plaintiffs, knew of a potential defect to its [product]," the plaintiffs "were not required to show ' "[i]dentical conditions" ' between the various incidents; rather, ' "[s]ubstantial

similarity is normally sufficient," ' and this 'determination "is primarily the function of the trial judge." ' " (*Colombo, supra,* 230 Cal.App.4th at p. 1475.)

The trial court admitted evidence of other incidents involving "the firing (misfiring), rectal occlusion, firing more than one time per stapler, and/or the stapler being lodged within the patient."[3] Ethicon argues that such incidents could result from a number of causes other than excessive force to fire, and therefore they are insufficiently similar to put Ethicon on notice of an excessive force to fire issue. Ethicon cites expert testimony that misfiring can be caused by thick tissue or the failure to fully disengage the Stapler's safety mechanism, and that a Stapler can get stuck by catching on a device used to keep the patient's anus open or on a lip of tissue in the rectum. However, there was also evidence that a misfire is an incomplete firing cycle, excessive force to fire can cause incomplete firing, misfiring can cause a Stapler to get stuck, and misfiring can cause a surgeon to fire more than once. The 2012 FDA recall notice stated difficulty firing the stapler can result in an "incomplete firing stroke" and "occlusion of the rectal canal." Thus, while there was evidence that the incidents reported to Ethicon could have resulted from other causes, there was also evidence they could have resulted from excessive force to fire. The trial court did not abuse its discretion in concluding that Ethicon "should therefore have been alerted to the fact that . . . the prior [incidents] . . . may have been due to a defect . . . ." (*Elsworth, supra,* 37 Cal.3d at p. 555 [rejecting argument that prior accidents were insufficiently similar because "other factors [besides a design defect] . . . might have been responsible for the accidents," where the plaintiffs introduced expert testimony that the design defect at issue in the plaintiffs' accident might have been the cause].)[4]

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[3] To the extent Ethicon contends incidents were admitted which did not meet this description, it forfeited this challenge by failing to so object below.

[4] Ethicon also argues Plaintiffs failed to demonstrate the incidents were sufficiently similar because they failed to submit evidence of the other patients' "hemorrhoid grade or pre-surgical diagnosis, the precise procedure that was being performed, the circumstances of the surgeon's firing of the stapler, and whether and to what extent the patient

Ethicon challenges the evidence of incidents involving different staplers: the PPH01 and STR10. There was ample evidence these staplers were sufficiently similar to the Stapler. Most significantly, the 2012 recall involved these two staplers in addition to the Stapler, indicating all three devices were susceptible to the excessive force to fire problem resulting from the lubrication change. There was also evidence the three devices "in functionality are very similar" and "use a common driver, driver guide and casing." The Stapler's lead design engineer testified the primary difference between the Stapler and the PPH10 is "delivered staple height." The trial court did not abuse its discretion in admitting evidence of incidents involving the PPH10 and STR10 staplers. (See *Hasson, supra,* 32 Cal.3d at pp. 403–404 ["The trial court plainly had a reasonable basis for admitting evidence of the numerous failures occurring in 1965 models for the purpose of showing the nearly identical 1966 models to be similarly defective. Plaintiffs were not required to prove that the 1965 system was exactly the same as the 1966 system."].)

Ethicon argues incidents predating the lubrication change leading to the 2012 recall should have been excluded. But Plaintiffs' theory was that the Stapler had force to fire issues even before that lubrication change, and the earlier incidents should have notified Ethicon that it needed to improve its inspection and monitoring systems. That the earlier incidents were not caused by a change in the lubrication system does not make them insufficiently similar for this purpose. Similarly, Ethicon argues some incidents were too remote in time, dating back to 2004. The Stapler's design did not change during this time and Ethicon provides no reason why the admission of incidents eight years before Kuhlmann's surgery is an abuse of discretion.

Ethicon also argues the trial court erred in admitting incidents taking place after Kuhlmann's surgery because they are not relevant to the issue of notice. Ethicon forfeited this challenge. At the hearing, the trial court observed that "notice . . . obviously would not include complaints that occurred after the incident," and the in

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experienced any complications from the surgery." Ethicon fails to cite evidence that these factors are relevant on the issue of Ethicon's notice of a defect.

limine order directed the parties to "meet and confer regarding any limiting instructions, for example regarding complaints after the date of the subject incident." Ethicon does not contend it requested such a limiting instruction and the challenge is thus forfeited. Even if it were preserved, we would find the error harmless in light of the numerous incidents predating Kuhlmann's surgery which were properly used as evidence of notice.

Finally, Ethicon argues use of the other incidents as a basis for the punitive damages award violates its due process rights. (See *Holdgrafer v. Unocal Corp.* (2008) 160 Cal.App.4th 907, 928 [" 'Due process does not permit courts, in the calculation of punitive damages, to adjudicate the merits of other parties' hypothetical claims against a defendant under the guise of the reprehensibility analysis.' "].) The jury was properly instructed that "punitive damages may not be used to punish Defendant for the impact of its alleged misconduct on persons other than Plaintiff," and " 'we presume the jury follows its instructions . . . .' " (*Garcia v. ConMed Corp.* (2012) 204 Cal.App.4th 144, 162.)

In sum, the trial court did not abuse its discretion in finding much of the evidence of other stapler incidents sufficiently similar to Kuhlmann's surgery to be relevant on the issue of whether Ethicon had notice that the Stapler was defective and/or its inspection and quality control processes were inadequate. That Ethicon could (and did) argue the other incidents were not sufficiently similar does not render the admission an abuse of discretion.

B. *2007 Recall*

1. *Background*

Before trial, Ethicon filed a motion in limine to exclude evidence of the 2007 recall. Ethicon argued: "Here, plaintiffs contend that the subject PPH03 stapler possessed a specific manufacturing defect, i.e. an elevated force-to-fire. However, the reason for the 2007 recall was completely unrelated to an elevated force-to-fire; instead, it was concerned with the adhesive bonding agent used on the device. Additionally, there are no facts to indicate that the PPH03 stapler in this case functioned as described in the 2007 recall, and therefore, any evidence of the 2007 recall has zero relevance to any issue in

this case. Further, there is no evidence that the PPH03 stapler allegedly used on plaintiff was subject to the 2007 recall."

In opposition to the motion, Plaintiffs argued the 2007 recall involved the same issue as the Stapler used in Kuhlmann's surgery, to wit, "incomplete firing stroke." (Emphasis omitted.) Plaintiffs argued the recall was thus relevant to show Ethicon had notice that its quality control procedures were inadequate: the 2007 recall "put Ethicon on notice as early as June 2007 that its quality control process was woefully inadequate. . . . The 2007 [r]ecall is relevant to show Ethicon had notice of its inadequate inspection process and failed to implement a proper inspection process in disregard of its consumers' safety." At the hearing, Ethicon argued the Stapler used in Kuhlmann's surgery was not subject to the 2007 recall, the 2007 recall was a voluntary recall and thus showed Ethicon's system "works," and admission of the evidence would be confusing and time-consuming.

The trial court denied Ethicon's motion to exclude the evidence but directed the parties to confer about an appropriate limiting instruction. The jury was instructed: "Evidence of the 2007 recall may be considered for the limited purpose, when I say limited purpose it means only for this purpose, for the limited purpose of whether or not Ethicon Endo-Surgery had notice that its quality control process was not adequate." On appeal, Ethicon does not contend it objected to this limiting instruction.

2. *Analysis*

Ethicon argues admission of the 2007 recall evidence was in error because the issue in the 2007 recall did not involve excessive force to fire. In opposition to Ethicon's in limine motion, Plaintiffs argued the similarity was an incomplete firing cycle. Ethicon fails to explain why this similarity was insufficient for the purpose asserted by Plaintiffs.

Ethicon also argues different quality control procedures at Ethicon's manufacturing facility would not have caught the problem leading to the 2007 recall because the defect—migrating glue—only occurred in a post-manufacture sterilization process at a separate facility. However, Ethicon neither submitted nor proffered evidence of this fact in its in limine motion or at the hearing on the motion. "Events in the trial

may change the context in which the evidence is offered to an extent that a renewed objection is necessary to satisfy the language and purpose of Evidence Code section 353," for example, when they reveal that the record at the time of the in limine motion did not permit the trial court to "determine the evidentiary question in its appropriate context." (*Morris, supra,* 53 Cal.3d at p. 190.) Because the record at the time of the in limine motion did not reveal to the trial court that the problem leading to the 2007 recall could not have been discovered by different quality control measures at Ethicon's manufacturing plant, Ethicon's motion in limine was not sufficient to preserve this objection.

II. *Juror Misconduct*

A. *Background*

On the fourth day of trial, an anonymous juror sent the following note to the trial court: "Does [Ethicon] and Dr. Shah want to continue after having/hearing all of these MedWatch reports[5] plus more than four patients having to receive a colostomy, even after the recall, more complaints insued [sic] plus a death! [¶] Objectively speaking — [¶] must we really go on?" Ethicon moved for a mistrial, which the trial court denied. Ethicon then requested the juror be identified, questioned in camera, and/or removed from the jury. The trial court denied these requests as well.

Instead, the trial court issued a lengthy admonition to the entire jury, which included the following: "I haven't been kidding when I have said repeatedly, please do not form or express any opinion about this case until all the evidence has come in. [¶] Plaintiffs go first. They put their case on, okay. And we know theirs is a lengthier case, so plaintiffs go first and it is their story that they are telling at this point. [¶] There will be other evidence that comes in, both from the corporate defendants and from Dr. Shah, and then there may be some back and forth, but right now it's a very, very limited window on the universe of testimony out there. [¶] And I'll remind you that you also have not been

[5] Ethicon submitted "MedWatch" forms to the FDA reporting complaints about staplers. These forms were included in Ethicon's files about other stapler incidents.

instructed about what the causes of action are and what each element is that has to be proven for each cause of action. [¶] Those instructions come at the end, and then you'll be tasked -- and it's not an easy job. It's not a knee jerk reaction and it's not an easy job. You will be tasked at the end of sitting down with those instructions with each cause of action and having to decide whether each element has been proven. [¶] And it's not until then that you can form or express any opinions." The court concluded, "I can't emphasize enough we're at the beginning or towards the beginning of this process, and there's going to be a lot more information that comes in, and you need to wait for that information to come in before you form or express an opinion about any of it. [¶] If you find that you're unable to do that, then, yes, I'd invite you to send me a note at some point and we can have a further discussion, but does everyone understand that? [¶] All right."

After the verdict, Ethicon filed a motion for a new trial on the ground, inter alia, of juror misconduct. Ethicon submitted a declaration from a trial consultant who interviewed Juror No. 3 after the verdict and averred: "In response to my question 'The jury sent a lot of notes and questions to the judge during the trial. Did you send any?', [Juror No. 3] said the following: [¶] 'Most of them. I was always asking questions. I really didn't know why we needed to be there. I sent a note about that. It seemed so obvious. Why must we go on? I sent a note asking that. And I know, we weren't supposed to make up our minds. The judge had said that we should keep an open mind about it all until we heard all the evidence; that we shouldn't make up our minds. But I did. I couldn't help it. I thought, can't we just move to a settlement or something?' "

In opposition to the motion, Plaintiffs submitted a declaration from Juror No. 3. Juror No. 3 described her conversation with the trial consultant: "One of her questions was about any notes that I had sent to the judge during trial. I told her I had asked many questions and sent many notes and, in response to her question, I described the note I sent during trial about whether the defendants wanted to go on with the trial. I described what I was thinking at the time I wrote the note. This was specifically in response to her question about notes, and my comments about how hard it was to keep an open mind

were limited specifically to my thought process at the time I wrote the note that I was describing." The declaration also stated Juror No. 3 took detailed notes throughout the trial, sent multiple notes to the trial court about the evidence, actively participated in deliberations, requested playback of witness testimony during deliberations, and "followed the judge's instruction to keep an open mind until the deliberations." Plaintiffs also submitted the declaration of the jury foreperson, who stated Juror No. 3 "appeared attentive, and took notes throughout the trial," participated fully in deliberations, and made no statement indicating she had prejudged the case or was biased against Ethicon.

The trial court denied Ethicon's motion without explanation.

B. *Analysis*

Ethicon argues the trial court erred in failing to examine Juror No. 3 after the note was sent and in denying the motion for a new trial. We disagree.

1. *Failure to Conduct an Inquiry*

"A juror's prejudgment of the case without hearing the evidence constitutes good cause to doubt his or her ability to perform the juror's duty and justifies discharge from the jury. [Citations.] When a court has been put on notice that there may be good cause to discharge a juror, it 'must conduct a sufficient inquiry to determine facts alleged as juror misconduct.' [Citation.] The trial judge is afforded broad discretion in deciding whether and how to conduct an inquiry to determine whether a juror should be discharged." (*People v. Clark* (2011) 52 Cal.4th 856, 971.)

After receiving Juror No. 3's note, the trial court issued a lengthy, detailed admonition to the entire jury reminding them not to prejudge the case, and inviting the jurors to contact the court if they were unable to do so. In light of the trial court's broad discretion, we cannot find error in the court's refusal to examine Juror No. 3 or otherwise conduct an inquiry.

2. *New Trial Motion*

"The trial court is vested with broad discretion to act upon a motion for new trial. [Citation.] When the motion is based upon juror misconduct, the reviewing court should accept the trial court's factual findings and credibility determinations if they are

supported by substantial evidence, but must exercise its independent judgment to determine whether any misconduct was prejudicial." (*People v. Dykes* (2009) 46 Cal.4th 731, 809.)

The parties dispute the admissibility of each other's declarations, as they did below. We will assume, without deciding, that the trial consultant's declaration submitted by Ethicon is admissible. With respect to Juror No. 3's declaration, Ethicon argues it is inadmissible under Evidence Code section 1150, subdivision (a), which provides: "Upon an inquiry as to the validity of a verdict, any otherwise admissible evidence may be received as to statements made, or conduct, conditions, or events occurring, either within or without the jury room, of such a character as is likely to have influenced the verdict improperly. No evidence is admissible to show the effect of such statement, conduct, condition, or event upon a juror either in influencing him to assent to or dissent from the verdict or concerning the mental processes by which it was determined." The portion of Juror No. 3's declaration explaining her response to Ethicon's trial consultant's question does not concern the mental process by which she reached her verdict. Instead, it is confined to a post-verdict event—her conversation with the trial consultant. Even assuming the rest of Juror No. 3's declaration is inadmissible, this portion is admissible.

The trial court could properly credit Juror No. 3's explanation that she intended her response to the trial consultant's question to be limited to the time period before she sent the note. Indeed, Juror No. 3's statement, as recounted by the trial consultant, is susceptible to this explanation. Because there was thus substantial evidence that Juror No. 3 did not prejudge the case after the trial court's lengthy admonition, the court did not abuse its discretion in denying a new trial on this ground.[6]

[6] We have resolved in respondents' favor all issues that could impact Dr. Shah. We accordingly deny as moot Dr. Shah's motion to dismiss the appeal as to her.

III. *Punitive Damages*

Ethicon argues the jury's finding that it acted with malice is not supported by substantial evidence or, in the alternative, the punitive damages award is excessive. We reject the first contention, but agree with the second.

A. *Malice*

1. *Legal Standard*

A plaintiff may recover punitive damages "where it is proven by clear and convincing evidence that the defendant has been guilty of oppression, fraud, or malice . . . ." (Civ. Code, § 3294, subd. (a).) " 'Malice' means conduct which is intended by the defendant to cause injury to the plaintiff or despicable conduct which is carried on by the defendant with a willful and conscious disregard of the rights or safety of others." (*Id.*, subd. (c)(1).) "The term ' "despicable," ' though not defined in the statute, is applicable to 'circumstances that are "base," "vile," or "contemptible." ' [Citations.] [¶] Under the statute, 'malice does not require actual intent to harm. [Citation.] Conscious disregard for the safety of another may be sufficient where the defendant is aware of the probable dangerous consequences of his or her conduct and he or she willfully fails to avoid such consequences. [Citation.] Malice may be proved either expressly through direct evidence or by implication through indirect evidence from which the jury draws inferences.' " (*Pfeifer v. John Crane, Inc.* (2013) 220 Cal.App.4th 1270, 1299 (*Pfeifer*).) " '[T]o establish malice, it is not sufficient to show only that the defendant's conduct was negligent, grossly negligent or even reckless. [Citation.] There must be evidence that defendant acted with knowledge of the probable dangerous consequences to plaintiff's interests and deliberately failed to avoid these consequences.' " (*Gawara v. United States Brass Corp.* (1998) 63 Cal.App.4th 1341, 1361.)

A corporate employer may be liable for punitive damages if "an officer, director, or managing agent of the corporation" committed, authorized, or ratified the malicious conduct. (Civ. Code, § 3294, subd. (b).) "[M]anaging agent" refers to "those corporate employees who exercise substantial independent authority and judgment in their

corporate decisionmaking so that their decisions ultimately determine corporate policy." (*White v. Ultramar, Inc.* (1999) 21 Cal.4th 563, 566–567.)

We review for substantial evidence the jury's finding that Ethicon acted with malice. (*Pfeifer*, *supra*, 220 Cal.App.4th at p. 1299.) The parties dispute whether our substantial evidence review is altered by the clear and convincing burden below. We will assume, without deciding, that our review " 'inquire[s] whether the record contains "substantial evidence to support a determination by clear and convincing evidence . . . ." [Citation.]' [Citation.] Under that standard, we review the evidence in the light most favorable to [respondents], give them the benefit of every reasonable inference, and resolve all conflicts in their favor, with due attention to the heightened standard of proof." (*Ibid.*)

2. *Analysis*

There was evidence that Ethicon knew, when it designed the Stapler, that excessive force to fire posed a risk to patient safety. The lead design engineer recommended that a plan be put in place to ensure that Staplers do not exceed a specified force to fire, and Ethicon went so far as to install a machine that tested the force to fire of every Stapler coming off the assembly line. Yet Ethicon never monitored these measurements or took any other such steps until after the 2012 recall. Ethicon argues there was no evidence that any managerial employee decided not to implement an inspection plan, suggesting the omission was simply negligent. But even though no employee admitted to making this decision, the jury could infer that such a decision was made.

Moreover, even if Ethicon inadvertently failed to implement a control plan for force to fire when it began manufacturing Staplers, Ethicon received numerous reports over the years which either indicated an excessive force to fire or identified issues which could be attributable to excessive force to fire.[7] The jury could conclude that these

[7] While Ethicon argues the reports did not indicate such a pattern, the jury could conclude otherwise. (See Part I.A.4, *ante*.)

reports notified Ethicon of force to fire issues, yet Ethicon failed to ensure that a control plan was in place to monitor force to fire. Finally, despite knowing the risks of excessive force to fire and knowing that insufficient lubrication would increase the force to fire, Ethicon failed to conduct tests before changing the method of applying lubrication to Staplers. Taken together, this evidence is sufficient to support the jury's determination that Ethicon acted with malice. (See *West v. Johnson & Johnson Products, Inc.* (1985) 174 Cal.App.3d 831, 869 ["the jury could reasonably have concluded (1) that adequate testing would have revealed an association between tampon use and vaginal infection, and ultimately between such use and menstrually related [toxic shock syndrome]; (2) that [the defendant's] testing was inadequate; (3) that [the defendant's] decision not to do any further testing, even when faced with continuing consumer complaints, was a conscious one; and (4) therefore, [the defendant] acted in conscious disregard of the safety of others"].)[8]

B. *Excessive Award*

"[T]he United States Supreme Court has determined that the due process clause of the Fourteenth Amendment to the United States Constitution places limits on state courts' awards of punitive damages, limits appellate courts are required to enforce in their review of jury awards." (*Simon v. San Paolo U.S. Holding Co., Inc.* (2005) 35 Cal.4th 1159, 1171 (*Simon*).) Courts apply "a three-factor weighing analysis looking to the nature and effects of the defendant's tortious conduct and the state's treatment of comparable

[8] Ethicon argues *West v. Johnson & Johnson Products, Inc.* is distinguishable because Ethicon did act in the face of complaints showing a pattern of excessive force to fire, by investigating and ultimately initiating the 2012 recall. Again, Plaintiffs argue earlier complaints showed such a pattern and the jury could so conclude. Ethicon also argues the malice finding cannot be supported by evidence that Ethicon failed to act quickly enough in recalling Staplers because such a finding is preempted by federal law. We do not rely on such evidence and the jury was instructed that it "may not consider the timeliness or conduct of either the 2007 or 2012 [Stapler] recalls in determining whether or not [Ethicon] acted with malice." Although Ethicon complains that Plaintiffs' closing statements nonetheless advanced this argument, it did not object and has therefore forfeited any challenge based on counsel's arguments.

conduct in other contexts. . . . [T]he constitutional 'guideposts' for reviewing courts are: '(1) the degree of reprehensibility of the defendant's misconduct; (2) the disparity between the actual or potential harm suffered by the plaintiff and the punitive damages award; and (3) the difference between the punitive damages awarded by the jury and the civil penalties authorized or imposed in comparable cases.' " (*Id.* at pp. 1171–1172.)

"In deciding whether an award of punitive damages is constitutionally excessive . . . , we are to review the award de novo, making an independent assessment of the reprehensibility of the defendant's conduct, the relationship between the award and the harm done to the plaintiff, and the relationship between the award and civil penalties authorized for comparable conduct." [Citations.] This '[e]xacting appellate review' is intended to ensure punitive damages are the product of the ' "application of law, rather than a decisionmaker's caprice." ' [Citation.] [¶] On the other hand, findings of historical fact made in the trial court are still entitled to the ordinary measure of appellate deference." (*Simon, supra,* 35 Cal.4th at p. 1172, fn. omitted.)

" '[T]he most important indicium of the reasonableness of a punitive damages award is the degree of reprehensibility of the defendant's conduct.' " (*Simon, supra,* 35 Cal.4th at p. 1180.) We have already concluded substantial evidence supports the jury's finding that Ethicon acted with conscious disregard of the safety of others by failing to ensure the force to fire of manufactured Staplers fell within the design specifications. However, there was no evidence Ethicon intended to cause injury or that Ethicon knowingly sold Staplers with excessive force to fire. Moreover, when it received reports of problems with Staplers, Ethicon did not ignore them. Instead, it had an established system in place to investigate individual reports and to review aggregate reports for trends—a system which led to two voluntary recalls. Ethicon implemented a pass/fail force to fire inspection for all manufactured Staplers before Plaintiffs' lawsuit was filed.

An example of " 'extremely reprehensible' " conduct is found in *Boeken v. Philip Morris Inc.* (2005) 127 Cal.App.4th 1640, 1694. The defendant manufacturer of "light" cigarettes knew its product "caused addiction and disease—and it added chemicals to the product to make it more addictive and easier to draw into the lungs, thus making it *more*

dangerous"; made "misleading statements and falsehoods about smoking, disease, and addiction"; and "was *still* marketing 'light' cigarettes at the time of trial, knowing that they may increase the risk of more serious cancers." (*Id.* at pp. 1692–1693.) *Izell v. Union Carbide Corporation* (2014) 231 Cal.App.4th 962 is another case involving "high reprehensibility." The defendant asbestos supplier knew that a brief exposure to low levels of asbestos causes cancer but "chose not to warn its customers about the risk of cancer . . . while seeking to maintain profits from the sale of asbestos." (*Id.* at p. 986.) Indeed, the company "continued sales of asbestos for more than decade after it internally recognized low levels of exposure could cause mesothelioma . . . ." (*Ibid.*) The degree of reprehensibility of Ethicon's conduct does not approach that of the defendants in these cases. We conclude Ethicon's degree of reprehensibility, while not negligible, is only moderate.

As for the relationship between the compensatory and punitive damages, the ratio in this case was approximately 7 to 1. "[R]atios between the punitive damages award and the plaintiff's actual or potential compensatory damages significantly greater than 9 or 10 to 1 are suspect and, absent special justification (by, for example, extreme reprehensibility or unusually small, hard-to-detect or hard-to-measure compensatory damages), cannot survive appellate scrutiny under the due process clause. . . . [¶] Multipliers *less* than nine or 10 are not, however, presumptively *valid* . . . . Especially when the compensatory damages are substantial or already contain a punitive element, lesser ratios 'can reach the outermost limit of the due process guarantee.' " (*Simon, supra,* 35 Cal.4th at p. 1182, fn. omitted.) The United States Supreme Court has "suggested that a ratio of one to one might be the federal constitutional maximum in a case involving . . . relatively low reprehensibility and a substantial award of noneconomic damages: 'When compensatory damages are substantial, then a lesser ratio, *perhaps only equal to compensatory damages,* can reach the outermost limit of the due process guarantee.' " (*Roby v. McKesson Corp.* (2009) 47 Cal.4th 686, 718 (*Roby*).) Plaintiffs' compensatory damages are substantial—nearly $10 million (only about $500,000 of

which was economic damages). In cases such as this, due process generally mandates a lesser ratio.[9]

The third factor—comparable civil penalties—"is less useful in a case like this one, where plaintiff prevailed only on a cause of action involving 'common law tort duties that do not lend themselves to a comparison with statutory penalties' [citation], than in a case where the tort duty closely parallels a statutory duty for breach of which a penalty is provided." (*Simon, supra,* 35 Cal.4th at pp. 1183–1184.) The only civil penalty cited by any party is Ethicon's reliance on 21 United States Code section 333(f)(1)(A), which limits civil penalties for violations of federal statutes and regulations governing medical devices to $1 million, even for multiple offenses if they are adjudicated in a single proceeding. To the extent this comparison is useful, it counsels in favor of finding the $70 million award excessive.

Plaintiffs argue Ethicon's financial condition justifies the punitive damages award. "It is certainly relevant for a reviewing court to consider the wealth of a defendant when applying federal constitutional limits to an award of punitive damages, thereby ensuring that the award has the appropriate deterrent effect." (*Roby, supra,* 47 Cal.4th at p. 719.) For example, "[i]n some cases, the defendant's financial condition may combine with high reprehensibility and a low compensatory award to justify an extraordinary ratio between compensatory and punitive damages. [Citation.] In other cases, especially those involving substantial compensatory awards, the level of deterrence may be limited . . . to that provided 'as a natural result of imposing damages over and above traditional

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[9] Plaintiffs argue the compensatory damage award did not include a punitive component in light of the jury instruction that compensatory damages may not include damages "to punish or make an example of any Defendant." However, to conclude due process warrants a lower ratio, it is not necessary to find that a substantial compensatory award contains a punitive element. (*Simon, supra,* 35 Cal.4th at p. 1182 ["Especially when the compensatory damages are substantial *or* already contain a punitive element, lesser ratios [than one to nine or ten] 'can reach the outermost limit of the due process guarantee.' " (italics added)]; *Roby, supra,* 47 Cal.4th at p. 718 [" '*When compensatory damages are substantial*, then a lesser ratio . . . can reach the outermost limit of the due process guarantee.' " (italics added)].)

compensatory damages, not from the imposition of sanctions in an individual case that are actually disabling to the defendant' [citation]; the state may have to partly yield its goals of punishment and deterrence to the federal requirement that an award stay within the limits of due process." (*Simon, supra*, 35 Cal.4th at pp. 1186–1187.) In any event, the defendant's wealth " ' "cannot justify an otherwise unconstitutional punitive damages award" ' [citation]." (*Roby*, at p. 719.) In this case, Ethicon's financial condition cannot justify the $70 million punitive award.

In light of Ethicon's moderate degree of reprehensibility and Plaintiffs' substantial noneconomic compensatory damages award, $70 million is a constitutionally excessive award. Ethicon argues the constitutional maximum is one times the compensatory damages. "To state a particular level beyond which punitive damages in a given case would be grossly excessive, and hence unconstitutionally arbitrary, ' "is not an enviable task . . . . In the last analysis, an appellate panel, convinced it must reduce an award of punitive damages, must rely on its combined experience and judgment." ' [Citation.] . . . . An appellate court should keep in mind, as well, that its constitutional mission is only to find a level higher than which an award *may not* go; it is not to find the 'right' level in the court's own view. While we must . . . assess independently the wrongfulness of a defendant's conduct, our determination of a maximum award should allow some leeway for the possibility of reasonable differences in the weighing of culpability. In enforcing federal due process limits, an appellate court does not sit as a replacement for the jury but only as a check on arbitrary awards." (*Simon, supra*, 35 Cal.4th at p. 1188.) We conclude the constitutional maximum in this case is two times the compensatory damages award, approximately $19.6 million.

DISPOSITION

The award of punitive damages is modified to two times the compensatory damages award. The judgment is otherwise affirmed. The parties shall bear their own costs on appeal.

SIMONS, Acting P.J.

We concur.

NEEDHAM, J.

BRUINIERS, J.

(A147945)